IN THE HIGH COURT OF AUSTRALIA
SYDNEY REGISTRY

NO S54 OF 2015

BETWEEN: **ASTRAZENECA AB**
First Appellant

ASTRAZENECA PTY LIMITED ACN 009 682 311
Second Appellant

HIGH COURT OF AUSTRALIA
FILED
04 MAY 2015
THE REGISTRY SYDNEY

AND: **APOTEX PTY LTD ACN 096 916 148**
Respondent

No S55 of 2015

BETWEEN: **ASTRAZENECA AB**
First Appellant

ASTRAZENECA PTY LIMITED ACN 009 682 311
Second Appellant

AND: **ACTAVIS PHARMA PTY LTD (FORMERLY WATSON PHARMA PTY LTD) ACN 147 695 225**
Respondent

No S56 of 2015

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BETWEEN: **ASTRAZENECA AB**
First Appellant

ASTRAZENECA PTY LIMITED ACN 009 682 311
Second Appellant

AND: **ASCENT PHARMA PTY LTD ACN 118 734 795**
Respondent

SUBMISSIONS OF THE COMMONWEALTH OF AUSTRALIA (SEEKING LEAVE TO INTERVENE)

Filed on behalf of the Commonwealth of Australia (Seeking Leave to Intervene) by:

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PART I FORM OF SUBMISSIONS

1. These submissions are in a form suitable for publication on the Internet.

PART II BASIS OF INTERVENTION

2. The Commonwealth of Australia (**Commonwealth**) seeks leave to intervene on the basis that:

   2.1. it is a non-party whose interests in other pending litigation[1] before the High Court, and the Federal Court of Australia, are likely to be affected substantially by the outcome of the proceedings in this Court; and

   2.2. the parties may not present fully the submissions the Court should have to assist it to reach a correct determination on the particular matters impacting upon the Commonwealth's interests.[2]

3. By its intervention (if leave is granted) the Commonwealth does not seek to support either party.

PART III REASONS WHY LEAVE TO INTERVENE SHOULD BE GRANTED

THE ISSUES IDENTIFIED: 'INVENTIVE STEP' AND *APOTEX V SANOFI*

4. By paragraph 2 of their respective Notices of Contention, each respondent contends that the judgment of the Full Court of the Federal Court ought be upheld on the basis determined by the primary judge, Jagot J, at (2013) 100 IPR 25; [2013] FCA 162, [198]-[223] consistently with the reasoning in *Apotex Pty Ltd v Sanofi-Aventis* (2009) 82 IPR 416 (***Apotex v Sanofi***) and *Aktiebolaget Hassle v Alphapharm Pty Ltd* (2002) 212 CLR 411 (***Alphapharm***). That part of her Honour's judgment, headed 'The "starting point" issue' concerned the determination of whether, pursuant to s 18(1)(b)(ii) of the *Patents Act 1990* (the **1990 Act**), the 'invention... so far as claimed in any claim...involves an inventive step'.

[1] Sanofi-Aventis & Ors v Apotex Pty Ltd (S 326 of 2014) – an application for special leave to appeal to the High Court of Australia; Apotex Pty Ltd v Sanofi (formerly Sanofi-Aventis), proceedings NSD 1639 of 2007 (Federal Court of Australia).

[2] *Roadshow Films Pty Ltd & Ors v iiNet Limited [No 1]* (2011) 248 CLR 37 at 38-39 [2] - [3]; *Levy v Victoria* (1997) 189 CLR 579 at 602, 603 (Brennan J).

5. In its submissions filed in support of that contention (**Apotex RS** [47]-[73]), Apotex contends:

5.1. (**Apotex RS** [47]), quoting Jagot J at [210], that 'the terms of the specification and claims inform the relevant starting point for the assessment of obviousness... Characterisation of the invention depends on the terms of the claims construed in the context of the specification as a whole';

5.2. (**Apotex RS** [55]) that for the purposes of assessing 'inventive step', the meaning of 'invention' in s 18(1) of the 1990 Act has the same meaning as in s 100(1) of the *Patents Act 1952* (Cth) (the **1952 Act**) (noting that s 100(1) of the 1952 Act governed the outcome in *Apotex v Sanofi*); and

5.3. (**Apotex RS** [59]) that 'in the context of the 1952 Act' the reasoning in *Apotex v Sanofi*, so far as it concerned the approach to assessing 'inventive step', was correct in its: (i) application of *Alphapharm and Lockwood Security Products Pty Ltd v Doric Productions Pty Ltd [No 2]* (2007) 235 CLR 173 (***Lockwood [No 2]***); and (ii) consideration of the terms of the specification in order to identify the invention claimed.

6. The respondents to S 55 and S 56 of 2015 adopt the submissions of Apotex on this point.[3]

7. In their Reply in S 54 of 2015, the appellants distinguish *Apotex v Sanofi* on the basis that it was decided under the 1952 Act. However, in the alternative, the appellants submit that *Apotex v Sanofi* is 'plainly wrong', thereby joining issue with the contentions of the respondents summarised at paragraph [5] above.

8. The effect of paragraph 2 of the Notices of Contention, and the submissions of the parties concerning it, is to raise an issue in these appeals as to the correctness of the reasoning in *Apotex v Sanofi* concerning s 100(1)(e) of the 1952 Act, and its application to determining the obviousness (*ie* lack of inventive step) of the invention claimed in the patent in suit in that case.

AFFECTION OF COMMONWEALTH'S LEGAL INTERESTS

9. In *Levy v Victoria* (1997) 189 CLR 579 Brennan J distinguished between an applicant for leave to intervene who had legal interests that would be 'affected directly by the proceeding – that is, one who would be bound by the decision albeit not a party' and a

[3] Respondents' (Actavis') submissions in S 555 and S 56 of 2015 (**Actavis RS**) at [51].

person who could claim only an 'indirect and contingent affection of legal interests'.[4] As to a person falling within the latter category, in order for such a person to satisfy the 'precondition' for leave to intervene, Brennan J observed that that person must demonstrate 'a substantial affection of [that person's] legal interest (as in the case of a party to pending litigation)'.[5] The distinction was adopted by this Court in *Roadshow Films Pty Ltd & Ors v iiNet Limited [No 1]*.[6]

10. In *Levy v Victoria,* leave was granted to certain media proprietors to intervene because, although none was in the category of a person whose legal interests were affected directly, each was able to show that its 'interests were likely to be substantially affected by the judgment in either this matter or in *Lange v Australian Broadcasting Corporation*'.[7] It is evident from the summary of argument given in the report of the case that the legal interests relied upon by the media proprietors were the continuation of their 'core business of publishing' (at CLR 585), their 'legitimate expectation, having ordered their affairs in accordance with the existing law, that they will be heard before being penalised for having done so' and their interests, as defendants to litigation, in which they had 'pleaded defences based on *Theophanous*' (at CLR 586). In *Levy*, Brennan CJ described the first set of interests as extra-curial, and he specifically noted that such interests are more indirect than the curial interest of a litigant in other pending proceedings.

11. By reference to the second suite of interests of the media proprietors in *Levy v Victoria:* (i) the Commonwealth has an interest in the three appeals pending before the Court; (ii) that interest is curial in the sense that it results from the Commonwealth's status as a litigant in other pending proceedings; and (iii) if the correctness of the reasoning or outcome in *Apotex v Sanofi* is to be the subject of consideration by this Court herein, the requirement for a 'substantial affection' of interests is 'demonstrable' (to use the language of Brennan CJ at p602) because the availability/existence of the Commonwealth's *whole* claim (not just part of a pleaded case as in *Levy*) is likely to turn on the outcome.

12. As to the matter stated at (ii) in the preceding paragraph, the Commonwealth is presently a claimant upon undertakings as to damages given by the entities who were

[4] *Levy v Victoria* (1997) 189 CLR 579 at 602 (Brennan CJ).

[5] *Levy v Victoria* (1997) 189 CLR 579 at 601-602 (Brennan CJ).

[6] (2011) 248 CLR 37 at 38-39 [2].

[7] *Levy v Victoria* (1997) 189 CLR 579 at 605 (Brennan CJ). The hearing of *Levy v Victoria* was adjourned and then resumed as a concurrent hearing with that of *Lange v Australian Broadcasting Corporation* (1997) 189 CLR 520 after the defendants in *Levy* sought leave to reopen and argue the correctness of *Theophanous v Herald & Weekly Times Ltd* (1994) 182 CLR 104 and *Stephens v West Australian Newspapers Ltd* (1994) 182 CLR 211: *Levy v Victoria* (1997) 189 CLR 579 at 584-585.

the respondents in *Apotex v Sanofi* (the **Sanofi Parties**). The undertakings by the Sanofi Parties were given at trial and on appeal in return for interlocutory injunctions, stays, and/or cross-undertakings (the **interlocutory restraints**).[8] The Commonwealth's claim upon the undertakings is pending in proceedings before Nicholas J in the Federal Court. The basis of the Commonwealth's claim, and its connection to the proceedings herein, require brief explanation.

13. The trial and appellate proceedings between Apotex and the Sanofi Parties concerned the validity of a patent (the **Clopidogrel Patent**) related to a medicinal drug known as 'clopidogrel'. In *Apotex v Sanofi* the Full Court of the Federal Court held that all claims in the Clopidogrel Patent were invalid on the ground of lack of inventive step (at [193]).[9] The Sanofi Parties unsuccessfully applied for special leave to appeal from that part of the judgment to this Court.[10]

14. The Clopidogrel Patent having been held invalid by the Full Court of the Federal Court, and special leave having been refused by this Court in March 2010, the Commonwealth notified the Sanofi Parties of its claim upon their undertakings in 2012 and filed its claim in the Federal Court in 2013.[11] In summary, the Commonwealth's claim is that by reason of the interlocutory restraints (at first instance and on appeal) Apotex delayed listing generic clopidogrel products on the Pharmaceutical Benefits Scheme (**PBS**) and the Repatriation Pharmaceutical Benefits Scheme (**RPBS**) pending determination of the Clopidogrel Patent's validity. The Commonwealth seeks compensation for the payments it made (or which it will be required to make) in respect of the supply of clopidogrel products under the PBS and RPBS and that the Commonwealth would not have made (or would not be required to make) if Apotex had not been restrained.

15. A precondition of the Commonwealth's claim upon the undertakings is the decision in *Apotex v Sanofi* that certain claims in the Clopidogrel Patent were invalid on the grounds of lack of inventive step. In deciding to bring its claim, the Commonwealth's understanding (reasonably and properly held) was that there had been a final resolution of the dispute regarding the validity of the Clopidogrel Patent.[12] The Commonwealth has since expended considerable resources and costs of approximately $2.7 million in

[8] Affidavit of Christopher John Pagent, sworn 24 April 2015 (**Pagent affidavit**) at [9], Exhibit CJP-1.

[9] The Full Court (at [193] Bennett and Middleton JJ) also held the following claims invalid for lack of novelty: (i) claim 1, to the extent the claim was to the d-enantiomer (but to the extent that the claim was to the pharmaceutically acceptable salts of the d-enantiomer, it was novel); and (ii) claims 10 – 11.

[10] [2010] HCATrans 059.

[11] Pagent affidavit at [13]-[14].

[12] Pagent affidavit at [29].

prosecuting its claim.[13]

16. If, in the course of these appeals, this Court were to reject or cast doubt upon the correctness of the outcome in *Apotex v Sanofi*, that would likely affect the Commonwealth's legal interest in its claim upon the Sanofi Parties' undertakings as to damages. In circumstances where the proceedings in which the Commonwealth claims upon the Sanofi Parties' undertakings – namely NSD 1639 of 2007 – are the very same proceedings as that from which the appeal in *Apotex v Sanofi* (NSD 1311 of 2008) was brought, the Commonwealth's legal interest is not an attenuated interest akin to that which might be held by a generic manufacturer currently involved in unrelated patent revocation proceedings about a different patent in the Federal Court. Although not a party to the substantive proceedings in *Apotex v Sanofi*, as a third-party claimant upon undertakings as to damages given in the course of those proceedings, the Commonwealth's claim *in* those proceedings flows directly, and not analogously, from the decision of the Full Court in *Apotex v Sanofi* and this Court's previous refusal of special leave to appeal from it.

17. Finally, there is an additional aspect to the relationship between the Commonwealth's legal interests in the *Apotex v Sanofi* proceedings and the pending appeals in this Court. On 24 April 2015 Nicholas J published a judgment dismissing, inter alia, an application by the Sanofi Parties for leave to further amend their Amended Points of Defence. Relevantly, the Sanofi Parties sought leave to amend their pleadings so as to enable them to argue that it would not be just and equitable, nor fair and reasonable, for the Federal Court to compensate the Commonwealth pursuant to the undertakings as to damages in circumstances where, according to the Sanofi Parties, the validity of their patent claims would have been upheld had the Full Court in *Apotex v Sanofi* adopted the same approach to the question of obviousness and, in particular, the 'starting point' issue, as was adopted by the Full Court below.[14] Nicholas J held that the argument that the Sanofi Parties should, or might, not be found liable to the Commonwealth because the Full Court's decision in *Apotex v Sanofi* was wrongly decided is not an argument that should be entertained by the Court in considering the Commonwealth's claim. Nicholas J held that the proposed argument necessarily involved a collateral attack upon the correctness of *Apotex v Sanofi* and was at odds with the general principle favouring finality in litigation: see *Commonwealth v Sanofi-Aventis* [2015] FCA 384 at [42], citing *De L v Director-General of NSW Department of Community Services & Anor* (1997) 190 CLR 207 at 215 and *DJL v The Central Authority* (2000) 201 CLR 226 at [90]. If

[13] Pagent affidavit at [25].

[14] A copy of the relevant paragraphs of the Sanofi Parties' proposed Further Amended Points of Defence is at Pagent affidavit, CJP-2.

this Court were to reject or cast doubt upon the correctness of the outcome in *Apotex v Sanofi*, it would confound the reasoning of Nicholas J and undermine the Commonwealth's present right to rely upon it.

COMMONWEALTH'S SUBMISSIONS ARE DISTINCT FROM THOSE OF THE PARTIES

18. Set out in Part V below are the submissions the Commonwealth would put as an intervener in the appeals.

19. The parties to the present appeals are concerned directly only with the 1990 Act and the particular patents in suit; however, in relation to paragraph 2 of the Notices of Contention they also advance submissions about the correctness of the reasoning in *Apotex v Sanofi* concerning: (i) the test for 'inventive step' under the 1952 Act; and (ii) application of that test, albeit to a different patent (the Clopidogrel Patent).

20. On those issues, the Commonwealth's submissions (in favour of the correctness of the *outcome* of *Apotex v Sanofi*) differ from those made in writing by the parties to the appeal.

21. Having regard to the peculiar circumstances which give rise to the potential for these appeals to affect the Commonwealth's legal interest in the compensation proceedings relating to *Apotex v Sanofi* – including the fact the relevant issue arises only by way of Notices of Contention – the Commonwealth has raised the possibility of a procedural direction that its application for leave to intervene not be determined until the close of primary oral argument between the substantive parties. By that point it may be clearer the extent to which (if at all) the resolution of the present appeals actually involves or requires consideration by this Court of the test for 'inventive step' under the 1952 Act, its application to the Clopidogrel Patent at issue in *Apotex v Sanofi* and/or the correctness of the outcome in that case.

PART IV LEGISLATIVE PROVISIONS

22. If the Court concludes it is necessary to reach paragraph 2 of the Notices of Contention and the correctness of *Apotex v Sanofi* under the 1952 Act, then in addition to the parties' statement of applicable provisions, the Commonwealth would add the following.

23. Section 100(1)(e) of the 1952 Act, which provided:

> ***Grounds of revocation***
>
> ***100(1)*** *A standard patent may be revoked, either wholly or in so far as it relates to any claim of the complete specification, and a petty patent may be revoked, on one or more of the following grounds, but on no other ground:*
>
> ...
>
> *(e) that the invention, so far as claimed in any claim of the complete specification or in the claim of the petty patent specification, as the case may be, was obvious and did not involve an inventive step having regard to what was known or used in Australia on or before the priority date of that claim...*

24. Section 230 of the 1990 Act, which provided:

> ***230 Repeal***
>
> *The* Patents Act 1952 *is repealed.*

25. Section 18(1)(b)(ii) of the 1990 Act, which is still in force and provides:

> ***18 Patentable inventions***
>
> *Patentable inventions for the purposes of a standard patent*
>
> *(1) Subject to subsection (2), an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim:*
>
> *(a)* ...
>
> *(b) when compared with the prior art base as it existed before the priority date of that claim:*
>
> *(i) is novel; and*
>
> *(ii) involves an inventive step; and*
>
> *(c)* ...

26. The provisions of Part VII of the 1952 Act also provide textual support for the Commonwealth's submissions below and are set out in full in an annexure to these submissions.

PART V ARGUMENT

SUMMARY OF COMMONWEALTH'S SUBMISSIONS

27. The Commonwealth advances the following propositions.

    27.1. The Court should strive to avoid, if possible, expressing a view or making a ruling on: (a) the applicability of the 'starting point' concept to the determination of 'obviousness' and 'inventive step' either under s 100(1)(e) of the 1952 Act or in the context of the Clopidogrel Patent at issue in *Apotex v Sanofi*; and/or (b) the correctness of the reasoning or outcome in *Apotex v Sanofi*.

10 27.2. If, contrary to 27.1, the Court finds it necessary to express a view or rule on those matters, the Court should conclude that the particular outcome in *Apotex v Sanofi* can be sustained on the facts of the particular patent in issue in that case, considered in the light of the 1952 Act.

28. The matter raised by paragraph 2 of the respondents' Notices of Contention falls to be considered only if the Court accepts the submissions of the appellants as to the construction of s 7(3) of the 1990 Act (as it stood prior to the amendments made by the *Patents Amendment Act 2001* (Cth)) and its application to what the parties refer to as 'the **051 Patent**'.

29. There is no equivalent to s 7(3) of the 1990 Act in the 1952 Act. The 051 Patent is
20 utterly unrelated to the Clopidogrel Patent in issue in *Apotex v Sanofi*.

AVOIDING (IF POSSIBLE) EXPRESSING A VIEW OR MAKING A RULING

Unnecessary and inappropriate to consider Notices of Contention if appellants fail on their grounds of appeal

30. If the Court rejects the appellants' grounds of appeal, it is unnecessary for the Court to decide the issue raised by paragraph 2 of the Notices of Contention. The Court should decline to do so in circumstances where:

    30.1. paragraph 2 of the Notices of Contention, as formulated by the respondents, raises issues extending to: (i) the application of a 'starting point' concept to
30 the determination of 'obviousness' and 'inventive step' under the 1952 Act; and (ii) the correctness of the reasoning in *Apotex v Sanofi* pursuant to the 1952 Act and the patent there in issue;

30.2. the provisions of the 1952 Act and the 1990 Act relevant to the determination of 'inventive step' are differently worded (*cf* s 100(1)(e) of the 1952 Act with s 18(1)(b) and ss 7(2) and (3) of the 1990 Act). Central to the operation of the test for 'inventive step' pursuant to the 1990 Act is s 7(3). There is no equivalent to s 7(3) in the 1952 Act;

30.3. the 1952 Act was repealed on 30 April 1991 by s 230 of the 1990 Act. Given the duration of patents under the 1952 Act and the fact that it has been 24 years since the repeal of the 1952 Act, it is unlikely that fresh observations by this Court on the test for inventive step pursuant to the 1952 Act would have much relevance, if at all, to future patent litigation;

30.4. in any event, the issues identified at 30.1 are indistinguishable from those the subject of the Sanofi Parties' unsuccessful application for special leave to appeal *Apotex v Sanofi* more than five years ago.[15] If there was ever an occasion for the Court to consider the precise terms of the 1952 Act and its application to the patent in suit in *Apotex v Sanofi* it was when they were squarely before the Court on the application for special leave to appeal. The arguments that could have been put against the correctness of *Apotex v Sanofi* on the issue of 'inventive step' were comprehensively addressed in the written outline of argument[16] and oral submissions[17] put on behalf of the Sanofi Parties. The submissions made by the appellants on the present appeals (as to the asserted incorrectness of *Sanofi v Apotex*) are to the same effect as those previously made by the Sanofi Parties in their application for special leave to appeal. In refusing special leave to appeal their Honours Gummow and Heydon JJ observed that they were 'not satisfied that there are sufficient prospects of success in overturning the result in [*Apotex v Sanofi*] respecting the operation of section 100(1)(e) of the *Patents Act 1952* (Cth) to warrant a grant of special leave'.[18] Even if there is any reason to doubt the correctness of their Honour's observations (which there is not), or otherwise to doubt the result in *Apotex v Sanofi* (which there is not), the Court has a fresh opportunity to decide whether to reconsider *Apotex v Sanofi* when it determines the Sanofi Parties' (extraordinary) second application for special leave to appeal filed in December 2014 and which is

[15] See Pagent affidavit, Exhibit CJP-3 (Sanofi Parties' written summary of argument), and Exhibit CJP-4 (transcript of hearing).

[16] Pagent affidavit, Exhibit CJP-3.

[17] Pagent affidavit, Exhibit CJP-4.

[18] *Sanofi-Aventis v Apotex Pty Ltd* [2010] HCATrans 059 at p.19; Exhibit CJP-4, p 60.

pending before the Court.[19] For reasons set out in the Commonwealth's submissions filed in support of its application for joinder to (or alternatively intervention in) that second special leave application,[20] it is inappropriate for the Court to grant the Sanofi Parties' novel application. If those submissions be accepted, it would be even less appropriate for the Court, in these unrelated appeals concerned with different (and differently worded) legislation, a different patent in suit, and without the record of *Apotex v Sanofi* before it, to express any view which casts doubt upon either the reasoning or the correctness of the result in *Apotex v Sanofi*; and

30.5. the Commonwealth has, on the faith of the finality of the decision in *Apotex v Sanofi* and subsequent to this Court's first refusal of special leave to appeal, expended considerable costs and resources in prosecuting its claims upon the Sanofi Parties' undertakings as to damages.[21] The result in *Apotex v Sanofi* – namely the invalidity of the Clopidogrel Patent – is a precondition to the Commonwealth's pending claim. In the ordinary case, adverse comment by this Court on one aspect of the reasoning of a five-year-old decision of an inferior Court would not be expected to affect the legal interests of parties to that decision, and even less the legal interests of non-parties *in* those proceedings. Ordinarily persons do not have any legal interests *in* proceedings to which they are not party. However the availability of interlocutory relief affecting non-parties, and the availability of procedures for courts to receive, and enforce, undertakings as to damages given by parties who receive the benefit of interlocutory restraints but are ultimately unsuccessful in the substantive proceedings, presents a more unique circumstance.

31. By way of summary, in circumstances where (i) *Apotex v Sanofi* is not squarely before the Court, (ii) if the appellants fail on their grounds of appeal the Court is not required to consider the issue raised by paragraph 2 of the Notices of Contention; (iii) unnecessary adverse comment by this Court concerning the correctness of the reasoning or result in *Apotex v Sanofi* would impact upon the legal interests of the Commonwealth; and (iv) the Sanofi Parties have already been refused special leave and a second application is presently pending, this Court ought not address paragraph 2 of the Notices of Contention.

[19] Pagent affidavit at [30]-[31], Exhibit CJP-5 (Sanofi Parties' written summary of argument).

[20] Pagent affidavit, Exhibit CJP-6.

[21] Pagent affidavit at [25].

If Notices of Contention are addressed, a very cautionary approach is warranted

32. Even if paragraph 2 of the Notices of Contention is to be considered, the Court should strive to avoid, if possible, expressing a view or making a ruling on: (a) the applicability of the 'starting point' concept to the determination of 'inventive step' either under the 1952 Act or in the context of the Clopidogrel Patent at issue in *Apotex v Sanofi*; and/or (b) the correctness of the outcome in *Apotex v Sanofi*.

33. The Commonwealth repeats and relies upon the matters set out above at paragraphs [30] – [31].

CORRECTNESS OF RESULT IN *APOTEX V SANOFI* (IF CONSIDERED NECESSARY TO RULE UPON)

34. If the Court finds it necessary to express a view or rule upon the determination of 'obviousness' and 'inventive step' either under the 1952 Act or in the context of the Clopidogrel Patent at issue in *Apotex v Sanofi*, the Court should conclude that the result in *Apotex v Sanofi* should be sustained on the facts of the particular patent in issue in that case when considered in the light of the 1952 Act.

The Clopidogrel Patent: relevant facts

35. The Clopidogrel Patent[22] contained 11 claims defining the invention.[23] It was admitted that the clopidogrel products that Apotex intended to make and sell would infringe claims 1, 3, 10 and 11 of the Clopidogrel Patent (assuming their validity).[24]

36. Claim 1 claimed the d-enantiomer of a racemate (PCR 4099, being the chemical compound known as 'clopidogrel') and its pharmaceutically acceptable salts.[25] A racemate comprises a dextro (or d-)enantiomer and a levo (or l-)enantiomer.[26] The Full Court of the Federal Court held that Claim 1 failed for lack of novelty insofar as it claimed the d-enantiomer.[27] Claims 10 and 11 also failed for lack of novelty.[28]

37. Thus the question of 'obviousness' and 'inventive step' was only relevant to the result in respect of:

[22] A copy of which appears at Pagent affidavit, Exhibit CJP-7.

[23] *Apotex v Sanofi* at [55] (Bennett and Middleton JJ).

[24] *Apotex Pty Ltd (formerly GenRx Pty Ltd) v Sanofi-Aventis* [2008] FCA 1194 at [5] (Gyles J).

[25] *Apotex v Sanofi* at [123] (Bennett and Middleton JJ).

[26] *Apotex v Sanofi* at [43] (Bennett and Middleton JJ).

[27] *Apotex v Sanofi* at [118] (Bennett and Middleton JJ).

[28] *Apotex v Sanofi* at [143] (Bennett and Middleton JJ).

37.1. that part of claim 1 which was for the pharmaceutically acceptable salts of the d-enantiomer;

37.2. claims 2 – 5, which were for specific salts of the d-enantiomer;[29] and

37.3. claims 6 – 9, which were process claims for obtaining the d-enantiomer.[30]

38. The concurrent findings of fact were that:

38.1. Sanofi-Aventis was the patentee of prior patents, including a prior Australian patent, which disclosed and claimed the racemate PCR 4099 and each of its enantiomers as suitable drugs for the purposes of platelet inhibition;[31]

38.2. despite such disclosure, the racemate PCR 4099 and each of its enantiomers had not come to form part of common general knowledge at the priority date;[32] and

38.3. if one had any of the racemate, the d-enantiomer or the l-enantiomer, then the selection of the integers to make the salts and the process for making the same were part of the common general knowledge as at the priority date and obvious.[33]

Characterising the 'invention' and resolving the question of obviousness

39. In the light of the findings of fact set out at paragraph [38] above, the question that arose in *Apotex v Sanofi* concerning obviousness was a narrow one: under the 1952 Act, where a person has disclosed an invention (and, indeed, obtained a patent for it) such that it is publically available but does form not part of common general knowledge, and the person makes a variant to that invention which is obvious, can the person claim a subsequent patent for the invention as varied and in doing so claim (in effect, reclaim) the credit for the original invention?

40. At least for the purposes of the patent in suit in *Apotex v Sanofi*, and by reference to the claims as made in that patent, the correct answer is 'no'.

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[29] *Apotex v Sanofi* at [119] (Bennett and Middleton JJ).

[30] *Apotex v Sanofi* at [179] (Bennett and Middleton JJ).

[31] *Apotex v Sanofi* at [70], [77], [106], [108] (Bennett and Middleton JJ)

[32] *Apotex v Sanofi* at [148] (Bennett and Middleton JJ).

[33] *Apotex v Sanofi* at [164] – [165] (Bennett and Middleton JJ), quoting the reasons of Gyles J in *Apotex Pty Ltd (formerly GenRx Pty Ltd) v Sanofi-Aventis* [2008] FCA 1194 at [35] – [36]; [174], [176], [177], [179] – [180] (Bennett and Middleton JJ).

41. That result flows from: *first*, identifying the precise 'invention' described and then claimed; and *second*, running that 'invention' through each of the hurdles set out in s 100(1). Those hurdles include that it be an invention that as at the priority date was: (e) not obvious and involved an inventive step; (f) not anticipated by a valid claim of a patent with an earlier priority date; (g) novel; and (h) useful.

First step: identifying the invention

42. A claimed invention that is anticipated by or disclosed in an earlier patent – as the first part of claim 1 of the Clopidogrel Patent did – will fail s 100(1)(f) (anticipation) and/or (g) (lack of novelty). A claim for an invention that is carved out from the earlier invention so as to survive the hurdles set by s 100(f) and (g) is self-evidently a narrower claim, being a claim only for the advance purportedly made from the earlier invention. If it survives the other hurdles in s 100(1) of the Act, it is that 'invention' which falls to be considered for obviousness/inventive step.

43. In determining what is the 'invention', it is the invention *so far as claimed* which is the focus of the inquiry (see the express terms of s 100(1)(e) of the 1952 Act). The terms of the specification, however, can assist in the process of coming to an understanding of what has been invented, as claimed. The relevance, indeed importance, of the specification to the characterisation task is unsurprising: s 40(1) of the 1952 Act requires that 'A Complete specification... (a) shall fully describe the invention'. In this process of characterisation, the so-called 'starting point' analysis is no more than an analytical tool that assists in the identification of that which is actually described and then claimed as the 'invention' (and which is thereafter to be run through the hurdles set out in s 100(1)) delineated from that which is taken for granted or assumed but not claimed as part of the invention.

44. As noted above, Sanofi was already the patentee – including of an Australian patent – which disclosed and claimed the racemate PCR 4099 and each of its enantiomers as suitable drugs for the purposes of platelet inhibition.[34] In order to claim an invention separate and distinct from that contained in the prior art (ie an invention that would pass the 'novelty' hurdle), it was necessary for the Clopidogrel Patent to identify and claim an invention distinct from the racemate PCR 4099 and its enantiomers. The concurrent findings of fact in *Apotex v Sanofi* were that 'the selection of PCR 4099 as the racemate to be resolved formed no part of this invention as described and claimed'[35] and that the process claims (claims 6-9) were 'not for the decision to obtain the enantiomer but to

[34] *Apotex v Sanofi* at [70], [77], [106], [108] (Bennett and Middleton JJ)

[35] *Apotex v Sanofi* at [152] (Bennett and Middleton JJ).

the means of doing so'.[36] Thus the relevant questions for the purposes of determining obviousness were whether, taking PCR 4099 and its d-enantiomer as the starting point:

44.1. its resolution into pharmaceutically acceptable salts (claim 1) was obvious?

44.2. its resolution into specific salts (claims 2 – 5) was obvious?

44.3. the process for obtaining the d-enantiomer (claims 6-9) was obvious?

45. On the concurrent findings of fact made in *Apotex v Sanofi* set out at paragraph [38.3] above, the only available answer to each of those questions was 'yes'. Each of those claimed 'inventions' was obvious in circumstances where the selection of PCR 4099 as the racemate to be resolved formed no part of the claimed invention such that, as the Full Court of the Federal Court identified, the 'hypothetical skilled worker' tasked with attempting to resolve the enantiomers of PCR 4099 must be assumed to have had 'that racemic mixture as the starting point'.[37] It is wholly unsurprising, therefore, that Gummow and Heydon JJ, in refusing the Sanofi Parties' first application for special leave, stated that they were not satisfied the Sanofi Parties had 'sufficient prospects of success in overturning the result' reached in *Apotex v Sanofi*.

Alphapharm

46. *Aktiebolaget v Hassle v Alphapharm* (2002) 212 CLR 411 (***Alphapharm***) exemplifies the orthodoxy and appropriateness of the approach described above. It was also a case to which the 1952 Act applied. A distinction was drawn in the patentee's submissions between (a) 'the nature of the problem' to be solved which the hypothetical worker was taken to have been given as the starting point for his task, and (b) the content of particular documents not shown to be part of common general knowledge. The patentee in *Alphapharm*, though very experienced patent counsel (Dr Emmerson QC), disclaimed any attempt to locate the inventive step in the invention disclosed and claimed in the prior patent:

> *The notional addressee is to be told the nature of the problem but is not provided with information not part of common general knowledge and obtainable only by testing. It is up to him to see whether he can work out a formulation given the characteristics of omeprazole. The addressee would not be given a copy of the compound patent.* [Gaudron J. Is not the nub of the case how you formulate the problem to the notional addressee?] *The problem is how do you formulate omezaprole, given its physical and chemical properties. The*

[36] *Apotex v Sanofi* at [179] (Bennett and Middleton JJ).

[37] *Apotex v Sanofi* at [160] (Bennett and Middleton JJ).

addressee is to be provided with information about those properties in order for him to understand the nature of the task of formulation, but no information not part of common general knowledge which can be derived only by attempting an actual formulation.[38]

47. The focus, therefore, was on the quality of the step from the known (the compound omeprazole which was known albeit not part of the common general knowledge) to what was claimed to be new (the formulation of omeprazole into a satisfactory pharmaceutical composition). The High Court cast no doubt on the appropriateness of this focus. And on the facts of the case, the patentee was able to establish an inventive step on going from the known to the new. Indeed the approach taken by the patentee was entirely consistent with Aickin J's comment in *Wellcome Foundation Ltd v VR Laboratories (Aust) Pty Ltd* (1981) 148 CLR 262 that 'the test is whether the hypothetical addressee faced with the same problem would have taken as a matter of routine whatever steps might have led from the prior art to the invention...'. See also *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd (No 2)* (2007) 235 CLR 173 at [127].

A statutory alternative available, but not taken, by the Sanofi Parties

48. Support for the result in *Apotex v Sanofi* is further obtained by considering provisions of Part VII of the 1952 Act regarding patents of addition relating to an improvement in, or modification of, an earlier invention already the subject of a patent by the same patentee (the **main invention**).[39]

49. Instead of applying for a standard patent in respect of the 'inventions' claimed in claims 1 – 9 of the Clopidogrel Patent, it was open to Sanofi, as the patentee of the earlier Australian patent[40] for the racemate PCR 4099 and its enantiomers,[41] to apply, pursuant to s 72, for a patent of addition in respect of those claims. That would have had the considerable advantage of engaging s 76 of the 1952 Act which provided, in effect, that a claim in a patent of addition was not invalid for obviousness by reason of the publication of the main invention before the priority date of the claim of the patent of addition. The very terms of s 76 contemplate that, but for its presence, obviousness under s 100(1)(e) would be assessed in the manner indicated above.

[38] *Alphapharm* at 435.4 (summary of argument).

[39] A matter expressly considered by Gyles J in considering the submission of the patentee: *Apotex Pty Ltd (formerly GenRx Pty Ltd) v Sanofi-Aventis* [2008] FCA 1194 at [105].

[40] Australian Patent No. 554358 which was laid open to inspection at the Australian Patent Office on 19 January 1984: *Apotex Pty Ltd (formerly GenRx Pty Ltd) v Sanofi-Aventis* [2008] FCA 1194 at [41] (Gyles J).

[41] A description of the claims made by the Australian prior art patent appears at *Apotex v Sanofi* [70] (Bennett and Middleton JJ).

50. In effect, the patent of addition route is the exception which enables an inventor to claim the credit for the same invention twice: once under the patent for the main invention; and secondly under the patent of addition, where the inventive step can lie in, or include, that which grounded the main invention.

51. For a person in the position of Sanofi, the patents of addition route can provide a safer (easier) route.

52. But the lower threshold for obviousness that applies if an applicant chooses to go down the patents of addition route comes at a price: pursuant to s 75 the term of a patent of addition is only for so long as the patent for the main invention remains in force. The 1952 Act therefore confronted patent applicants with a trade-off: the application of a lower threshold for the test of obviousness if the patents of addition route were taken, but at the cost of a shorter term; or a more demanding threshold for obviousness as the price of a longer term if the applicant sought (as Sanofi did) a free-standing standard patent for the claimed 'new' invention. Sanofi was free to choose the route it did, but once it sought a fresh standard patent with a fresh term that would extend beyond the term of the earlier Australian patent, it placed itself in the position of the claimant in *Alphapharm*: it needed to show that the step it had taken which gave its second patent novelty over the first, and thus qualified for a standard patent, was inventive. It failed to do so on the concurrent findings of fact set out at paragraph [38] above.

PART VI ESTIMATED HOURS

53. If granted leave to intervene, the Commonwealth estimates that it would require 20-30 minutes for the presentation of its oral argument.

Dated: 4 May 2015

.....	.....	.....
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Annexure to the Submissions of the Commonwealth of Australia (Seeking Leave to Intervene)

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Effect of patent

69. Subject to this Act, the effect of a patent is to grant to the patentee the exclusive right, by himself, his agents and licensees, during the term of the patent, to make, use, exercise and vend the invention in such manner as he thinks fit, so that he shall have and enjoy the whole profit and advantage accruing by reason of the invention during the term of the patent.

Extent of patent

70. A patent has effect throughout Australia.

Loss or destruction of patent

71. If a patent is lost or destroyed, or its non-production is accounted for to the satisfaction of the Commissioner, the Commissioner may cause a duplicate of the patent to be sealed.

PART VII—PATENTS OF ADDITION

Part not to apply to petty patents

71A. In this Part "patent" does not include a petty patent.

Application for patent of addition

72. Where a patent for an invention has been applied for or granted and a person (being the applicant or patentee or some other person with the consent of the applicant or patentee) applies for a further patent in respect of an improvement in, or modification of, the invention (in this Part referred to as "the main invention"), the first-mentioned person may, in his application for the further patent, request that the term of that patent shall be the same as that of the patent for the main invention or so much of that term as is unexpired.

Grant of patent of addition

73. (1) Where an application containing such a request is made, the Commissioner may, subject to this Part, grant a patent, and the term of the patent so granted shall, subject to this Part, be the term referred to in section 72.

(2) A patent shall not be granted as a patent of addition unless the date of lodging of the complete specification was the same as, or later than, the date of lodging of the complete specification in respect of the main invention.

(2A) An application for a patent of addition and the complete specification lodged in respect of that application shall not be examined before a request is made for the making of an examination of the application for the patent for the main invention and of the complete specification lodged in respect of that application.

(3) A patent of addition shall not be sealed before the sealing of a patent for the main invention.

(4) An appeal lies to the Federal Court from a decision of the Commissioner under this section.

Revocation of patent and grant of patent of addition in lieu

74. Where an invention, being an improvement in, or modification of, an original invention, is the subject of an independent patent and the patentee in respect of the independent patent is also the patentee in respect of the patent for the original invention, the Commissioner may, on an application made by the patentee, revoke the independent patent and grant a patent of addition in respect of the improvement or modification bearing the same date as the date of the independent patent so revoked.

Duration of patent of addition

75. (1) A patent of addition shall remain in force so long as the patent for the main invention remains in force, and no longer, but may be extended under Part IX for any period for which the patent for the main invention is extended.

(2) A fee is not payable in respect of the renewal of a patent of addition.

(3) If the patent for the original invention is revoked or surrendered, the patent of addition shall, unless a prescribed court in the case of revocation, or the Commissioner in the case of surrender, otherwise orders, become an independent patent, and the fees payable after the patent of addition becomes an independent patent, and the dates when they become payable, shall be determined by its date, but its duration shall not exceed the unexpired term of the patent for the main invention.

Validity of patent of addition

76. Objection shall not be taken to an application for a patent of addition, so far as the invention is claimed in any claim of the complete specification, and a patent of addition, so far as the invention is so claimed, is not invalid, on the ground only that the invention, so far as claimed in any claim of the complete specification, is obvious and does not involve an inventive step, having regard to—

(a) the publication of the main invention before the priority date of that claim but after the priority date of the claim of the specification of the main invention defining the invention the improvement in which, or the modification of which, is the subject of the first-mentioned claim, or, if there are two or more claims defining that invention, after the priority date of whichever of those claims has the earlier or earliest priority date; or

(b) the use of the main invention during that period.